

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA**

DIANE STANESIC,)	
)	
Plaintiff,)	
)	CASE NO. _____
vs.)	
)	
EXACTECH, INC. and)	
EXACTECH US, Inc.,)	
)	
Defendants.)	COMPLAINT AND JURY DEMAND
)	

COMPLAINT AND JURY DEMAND

COMES NOW the Plaintiff, DIANE STANESIC, by and through undersigned counsel and submits this Complaint and Jury Demand against Exactech, Inc. (“Exactech”) and Exactech US, Inc. (“Exactech US”) (collectively “Defendants”) for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to Plaintiff Diane Stanesic, as a result of her injuries suffered as a direct and proximate result of Defendants’ designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting and/or selling the defective device sold under the name “Optetrak” total knee replacement system (hereinafter “Optetrak” or “Defective Device”). In support, Plaintiff alleges the following:

INTRODUCTION

1. Defendants, directly or through their agents, apparent agents, servants, and/or employees designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device for the use as a total knee replacement.

2. Defendants concealed, and continue to conceal, their knowledge of the Defective Device's unreasonably dangerous risks from Plaintiff, Plaintiff's medical providers, other consumers, and the medical community at large.

3. As a result of the defective nature of the Optetrak knee replacement procedure, persons who were implanted with a Defective Device, including Plaintiff, have suffered, and may continue to suffer, severe and permanent personal injuries, including painful knee revision surgery to remove or revise the Defective Device, continued rehabilitation, medical care, and possible additional surgeries.

4. The Plaintiff Diane Stanesic's left knee was implanted with the Optetrak Knee replacement system. After being implanted with the Defective Device, Plaintiff experienced pain and other symptoms, and as a direct and proximate result of the Defendants' actions and inaction, Plaintiff required revision surgery to remove the Defective Device. The Optetrak knee replacement implant was defective, unreasonably dangerous, defectively designed, defectively manufactured, and caused permanent injury and damage to Plaintiff.

5. Plaintiff could not reasonably have discovered the injury and its cause before the date of the revision surgery and/or the date of any recall notification to Plaintiff and her doctor, as no recall has occurred and Defendants continue to deny responsibility for the device's premature failure due to premature polyethylene wear and/or tibial base plate loosening.

6. The components of the device were defective, unreasonably dangerous and failed, resulting in loosening, malpositioning of the implant, and rubbing/wear of the components causing instability, limited mobility, swelling and pain. This was initially discovered upon revision surgery on Plaintiff's left knee.

7. Plaintiff brings this action for personal injuries suffered as a proximate result of being implanted with the Defective Device. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies provided to Plaintiff under equity and law as a result of injuries caused by the implantation of the Defective Device and for Defendants' conduct.

PARTIES

8. At all times relevant hereto, Plaintiff Diane Stanesic was a resident and citizen of West Mifflin, Allegheny County, Pennsylvania. As a result of the implantation of the Defective Device, Plaintiff suffered personal and economic injuries and sought treatment for the effects of the injuries that were the direct and proximate result of the implantation of the Defective Device and Defendants' conduct.

9. Defendant Exactech, Inc. is a for-profit Florida corporation with its principal place of business at 2320 NW 66th CT, Gainesville, Florida, 32653. Exactech's stated business purpose is to "develop, manufacture, market, distribute and sell orthopedic implant devices, related surgical instrumentation and biologic services to hospitals and physicians in the United States and internationally"¹ and to introduce its products, including the Defective Device, into interstate commerce, either directly or indirectly through third parties or related entities.

10. Exactech US, Inc., a wholly owned subsidiary of Defendant Exactech, Inc., is registered to do business in Georgia and has a registered agent at National Registered Agents, 289 S. Culver Street, Lawrenceville, Georgia 30046 and can be served at that address. Defendant Exactech Inc.'s "U.S. sales and distribution activities are conducted by [its] wholly owned

¹ Exactech 2015 Form 10-k, p. 2. <https://www.exac.com/resource-library/investors/recent-filings/10-k-annual-report-1>

subsidiary Exactech US, Inc.”² and Exactech U.S., Inc. is engaged in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing its products, including the Defective Device, into interstate commerce, either directly or indirectly through third parties or related entities.

11. Collectively, Exactech, Inc. and Exactech US, Inc. are referred to in this pleading as “Exactech” or “Defendants.”

JURISDICTION AND VENUE

12. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy exceeds \$75,000 exclusive of interest and costs, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

13. The Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

14. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Defective Device, within the State of Pennsylvania with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

² *Id.*

15. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and/or misleading information about the Defective Device to health care professionals in the State of Pennsylvania, including Plaintiff's health care professionals, with a reasonable expectation that such information would be used and relied upon by health care professionals throughout the State of Pennsylvania, including but not limited to:

- a. false representations of duration and survival of the components lasting longer than other knee implants because of proprietary use of materials and processes to give superior wear characteristics; and/or
- b. false claims of greater forgiveness to sub-optimal implantation conditions.

16. Defendants engaged in substantial business activities in the State of Pennsylvania. At all relevant times, Defendants transacted, solicited, and conducted business in Pennsylvania through their employees, agents, and/or sales representatives and derived substantial revenue from such business in Pennsylvania. Said activities included the promotion, sale, and use of the Defective Device.

17. Further, Defendants committed torts in whole or in part against Plaintiff in the State of Pennsylvania. As such, this Court has personal jurisdiction over all named defendants.

18. Venue is proper within this district pursuant to 28 U.S.C. § 1391(b)(2) because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL BACKGROUND

19. At all times material hereto, Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device under various versions of the name "Optetrak."

20. Upon information and belief, the first Optetrak knee device became available to be implanted in a patient in 1994.

21. Since 1994, Defendants have obtained 510(k) clearance for various Optetrak devices and tibial inserts including the Optetrak PS, Optetrak Hi-Flex PS, Optetrak Finned Tibial Tray, Optetrak Offset Tibial Tray, Optetrak RBK Tibial Insert, Optetrak RBK Tibial Tray, Optetrak CR Slope, and Optetrak Logic.

22. A typical knee replacement surgery, referred to as a total knee arthroplasty (“TKA”), is performed under general anesthesia. The primary indication for TKA is to relieve severe pain associated with arthritis and may also be used to correct knee trauma or minor knee deformities.

23. During the TKA procedure, the surgeon will make an approximately 8-10 centimeter incision on the front of the leg over the knee.

24. The surgeon will then prepare the femur portion of the knee, the distal femur. This process includes removing any diseased bone and drilling a hole in the femur in which to implant the femoral component of the device. The surgeon will then place a femoral implant onto the distal femur using surgical cement.

25. Next, the surgeon will prepare the proximal tibia, the bone located at the bottom of the knee. The tibial preparation includes removing diseased bone, properly aligning the tibial tray, and drilling a hole in which to implant the tibial tray. The tibial tray is then implanted using surgical cement.

26. A third product, the tibial insert, is a polyethylene product implanted between the femoral implant and tibial tray.

27. Defendants promoted their Optetrak devices as a system with three decades of clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stresses.

28. The allegations in this Complaint relate to the early failure of the Defective Device, its tibial tray and its polyethylene component.

29. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold Optetrak tibial trays with a design Defendants referred to as “finned.”

30. Upon information and belief Defendants became aware of a high rate of early failures with the “finned” Optetrak products.

31. In 2012, “Poor results of the Optetrak cemented posterior stabilized knee prosthesis after a mean 25-month follow-up: Analysis of 110 prostheses” was published in Orthopaedics and Traumatology, volume 98, issue 4, pages 413-420. The article concluded “the small size of the tibial keel does not seem to resist the stresses applied by the ultracongruent shape of the posterior stabilization of this implant and the increase in intercondyloid eminence height.”

32. The Australian joint registry is an authoritative source that the medical community and industry look to in calculating prosthetic survival rates.

33. In the 2016 Australian Registry Annual Report, the compared revision of TKA that had a primary diagnosis of osteoarthritis (“OA”), which is 97% or all diagnosis, as installed in the Plaintiff, was reported as:

- a. Not statistically significant rate of revision at 1 year;
- b. Optetrak was statistically significant (range not overlap; $3.9 > 2.8$) at 3 years;

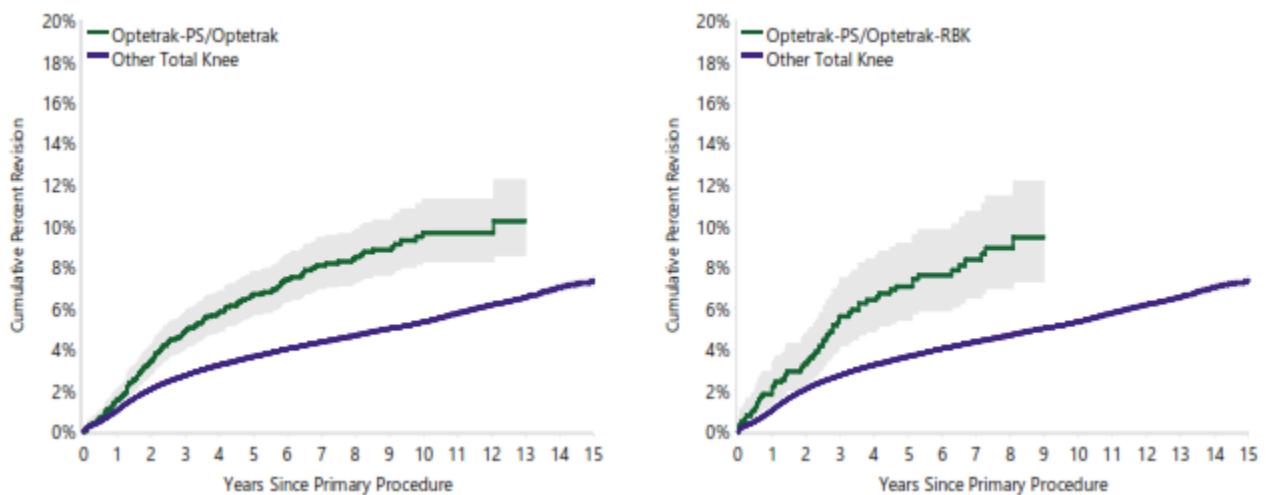
- c. Optetrak was statistically significant (range not overlap; $56 > 3.7$) at 5 years;
- d. Both Optetrak and Optetrak-RBK had significantly increased rates of revision at 7 years.

Table KT6 Cumulative Percent Revision of Primary Total Knee Replacement by Primary Diagnosis

Primary Diagnosis		N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	15 Yrs
Osteoarthritis		17213	482373	1.0 (1.0, 1.1)	2.7 (2.7, 2.8)	3.6 (3.6, 3.7)	4.4 (4.3, 4.4)	5.3 (5.2, 5.4)	7.3 (7.1, 7.6)

Femoral Component	Tibial Component	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	15 Yrs
Optetrak-PS	Optetrak	159	2398	1.5 (1.1, 2.1)	4.7 (3.9, 5.7)	6.6 (5.6, 7.8)	7.9 (6.7, 9.2)	9.6 (8.1, 11.4)	
Optetrak-PS	Optetrak-RBK	37	720	1.6 (0.9, 2.8)	3.9 (2.7, 5.9)	5.3 (3.7, 7.5)	6.9 (4.9, 9.7)		

34. The Australian registry identifies the Optetrak as an implant with a higher than expected rate of revision. The figures below are the survival curves where the 95% confidence intervals do not overlap. The hazard ratio reported is high. The p value of $p < 0.001$ means that the



2016 Australian Registry Annual Report Pg 343

Femoral/Tibial	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs	Hazard Ratio, P Value
Optetrak-PS/Optetrak-PS	13	55	405	3.21	Entire Period: HR=5.86 (3.40, 10.09), $p < 0.001$

2016 Australian Registry Annual Report Pg 348

35. Put into perspective, the cumulative percent revision of primary total knee replacement with cemented fixed bearing Optetrak (the type as implanted in the Plaintiff) as compared with all other reported cemented knees was:

- a. the second worst mean percent failure rate of 4.7% as compared with all other cemented knees at 3 years;
- b. The Optetrak bearing tied for worst failure rate of 6.6% at 5 years as compared to all other cemented knees;
- c. The Optetrak fixed bearing had the worst failure rate with a mean of 7.9% at 7 years as compared to all other cemented knees;
- d. The Optetrak fixed bearing has worst failure rate with a mean of 9.6% at 10 years, as compared to all other knee implants.³

36. By 2012, Defendants were aware that Optetrak knee implants were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicate instances of revision due to “loose tibial component”, “aseptic loosening”, “polyethylene wear”, “pain and visible loosening”, and “pain, limited mobility, knee swelling and sensitivity” due to a “loose” joint. These early onset failure MAUDE reports are representative of the increased rate of incidents of which Defendants had become internally aware.

37. Upon information and belief, instead of warning consumers and the medical community about the increased failure rates with its finned Optetrak devices, Defendants engaged in a “silent recall” campaign where they slowly replaced all finned tibial trays with a

³ These statistics in the chart are expressed as the “Optetrak” v. the “Optetrak-RBK” which is the rotational bending knee. This tibial plate also has a very high failure rate and is similar in design but has the polyethylene insert that rotates.

new, more substantial design, referred to as “fit” trays and change of the polyethylene insert. Concurrent with this strategy of product replacement, Defendants also engaged in a campaign of misinformation where any incidents of early onset failure were blamed on surgeon specific factors instead of acknowledging problems with the tibial tray and polyethylene insert product itself.

38. In 2015, Defendants had over \$241 million in sales across all product lines.⁴ Further, Defendants state in their 2015 Form 10-K, “to better meet the demand for revision surgeries, we began the initial launch of a new revision knee system in 2015.”⁵

39. Of the more than \$241 million in sales, knee device sales accounted for over \$70 million in sales, or 29.3% of all Defendants’ sales in 2015.⁶

40. In 2016, Defendants’ revenue increased by 7%, up to \$257.6 million with knee device sales increasing 4%.⁷ Knee device sales for the fourth quarter of 2016 accounted for \$19.8 million of this amount.⁸

41. According to Exactech CEO and President David Petty, the increases in knee device revenue “reflect excellent surgeon acceptance of Exactech innovations, including our three new revision systems.” Mr. Petty further stated that he anticipates the “revision knee rollout in the fourth quarter” of 2016 will “carry momentum into 2017.”⁹

42. A new Exactech knee implant, called “Truliant”, is anticipated for release in the second half of 2017.¹⁰ Truliant received FDA 510(k) clearance, K170240, on February 23, 2017.

⁴ See Exactech, Inc. Form 10-K for the fiscal year ended December 31, 2015, <https://www.exac.com/resource-library/investors/recent-filings/10-k-annual-report-1>

⁵ *Id.* at p. 4.

⁶ *Id.*

⁷ See Exactech, Inc. Form 8-K dated February 21, 2017, <https://www.exac.com/resource-library/investors/recent-filings/8-k-current-report-12>

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

43. Despite Defendants' claims in its promotional materials of over 30 years of successful outcomes with knee devices, Defendants knew of an unacceptably high early failure rate of their Optetrak knee implants.

PLAINTIFF SPECIFIC ALLEGATIONS

44. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device.

45. A defectively designed and manufactured Optetrak knee implant left the hands of Defendants in its defective condition. Defendants delivered the Defective Device into the stream of commerce and allowed it to be implanted in a total knee arthroplasty in Plaintiff.

46. As a direct and proximate result of Defendants placing the Defective Device into the stream of commerce, Plaintiff required left knee revision surgery.

47. As a direct and proximate result of Defendants placing the Defective Device into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; past, present and future medical, hospital, rehabilitative and pharmaceutical expenses and other related damages.

48. Based on information and belief, Defendants' knee implant devices are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or methods, facilities, or controls used for their manufacture, packaging, storage or installation and are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

49. Based on information and belief, Defendants' knee implant devices are misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

50. Based on information and belief, Defendants' knee implant devices are adulterated pursuant to 21 U.S.C. § 351 because Defendants failed to establish and maintain Current Good Manufacturing Practices ("CGMP") for its knee implant devices in accordance with 21 CFR § 820 *et seq.*

51. Based on information and belief, Defendants failed to establish and maintain CGMP with respect to quality audits, quality testing, surveillance related to failures and process validation for its knee implant devices.

52. Defendants had a duty to follow Current Good Manufacturing Practices. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' knee implant devices were defective and failed, resulting in injuries to the Plaintiff.

53. If Defendants had complied with the federal requirements regarding CGMP, Defendants' knee implant devices would have been manufactured properly and would not have resulted in injuries to the Plaintiff.

FIRST CAUSE OF ACTION
NEGLIGENCE

54. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

55. Defendants had a duty to exercise reasonable care in the design, development, formulation, testing, manufacture, marketing, sale and distribution of the Defective Device into

the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events to its users as well.

56. Defendants had an obligation to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, post market surveillance, preparing for use, including a duty to warn Plaintiff and other consumers of the risks and dangers associated with the Defective Device that were known or should have been known to Defendants at the time of the sale to the Plaintiff and otherwise distributing the Defective Device.

57. Defendants' acts and omissions constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

58. The Defendants owed Plaintiff and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling the Defective Device, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn Plaintiff and other consumers of the dangers associated with the Defective Device.

59. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of the Defective Device.

60. Defendants breached their duty and failed to exercise ordinary care and/or were negligent, reckless and/or wanton in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the Defective Device into interstate commerce because Defendants knew or should have known that these products would cause significant bodily harm and were not safe for use by consumers.

61. Defendants failed to exercise ordinary care in the labeling of the Optetrak system and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff, regarding the risk of serious injury, including tibial base plate loading, premature polyethylene wear, and risk for early revision surgery.

62. Defendants knew or should have known that Plaintiff could suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

63. Despite the fact that Defendants knew or should have known that the Defective Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Defective Device for implantation into consumers.

64. Defendants failed to exercise due care under the circumstances, and their negligence and recklessness includes the following acts and omissions:

- a. Failing to properly and thoroughly test the Defective Device before releasing the device to market;
- b. Failing to properly and thoroughly analyze the data resulting from the premarketing tests of the Defective Device;
- c. Failing to conduct sufficient post-market testing and surveillance of the Defective Device;
- d. Designing, manufacturing, marketing, advertising, distributing, and selling the Defective Device to consumers, including Plaintiff, without an adequate warning of the dangerous risks of the Defective Device;
- e. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Defective Device in accordance with good design practices;

- f. Failing to notify and warn the public including Plaintiff of reported incidents involving injury, and the negative health effects attendant to the use of the Defective Device, thus misrepresenting the safety of the product;
- g. Failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Defective Device;
- h. Failing to exercise due care when advertising and promoting Defective Device;
- i. Disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Defective Device;
- j. Continued to aggressively promote the Defective Device even after Defendants knew or should have known of the unreasonable risks from implantation;
- k. Failed to provide information that accurately reflected the high early failure rate of the Defective Device; and
- l. Downplayed, or otherwise suppressed, through aggressive marketing and promotion the risks associated with the implantation of the Defective Device.
- m. Failing to make timely and adequate corrections to the manufacture, design and formulation of the Defective Device so as to prevent and/or minimize the problems suffered by use of the Defective Device;
- n. Failing to use due care in training and informing health care providers on proper surgical technique and limitations of the device so as to avoid injuries and premature device failure;

- o. Failing to use due care in the testing, formulation, inspections, distribution sale and instructions regarding the product at all times prior to Plaintiff's injuries having manifested themselves;
- p. Continuing to negligently manufacture, market, advertise, and distribute the Defective Device after the Defendants knew or should have known of its adverse effects and/or the increased early onset failure rates, and
- q. Being otherwise careless, reckless and negligent.

65. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Device, and otherwise distributing the Defective Device.

66. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Defective Device, Plaintiff was implanted with the Defective Device and has suffered , and will continue to suffer in the future severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent physical injury and damage, including instability, loss of balance, and immobility, as well as pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

67. Had Defendants properly disclosed the risks associated with early failure of the Defective Device, Plaintiff and Plaintiff's surgeon would have avoided the risk of implantation

of the Defective Device and/or would have medically monitored Plaintiff differently after the Defective Device was implanted in order to minimize and/or mitigate the damages which would result from the Defective Device.

68. Plaintiff contends that the conduct of the Defendants, as described above, including, but not limited to, their failure to adequately design and manufacture, as well as their continued marketing and distribution of the Defective Device when they knew or should have known of the serious health risks the device created and/or the failure to comply with federal requirements, is attended by circumstances of oppression, fraud, malice, willfulness, wantonness, and constitutes a conscious, reckless and flagrant disregard for human life.

69. Defendants' conduct, as described above, was reckless. Defendants risked the health of consumers and users of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign or re-label the Defective Device, or to warn or inform the unsuspecting consuming public.

70. The Defendants are liable to Plaintiff for injuries caused by their willful conduct in failing to disseminate information related to the early failure of the Defective Device.

71. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a painful knee revision surgery and other related health complications. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

SECOND CAUSE OF ACTION
MANUFACTURING DEFECT

72. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs excluding the previously named first and second causes of action, with the same force and effect as if more fully set forth herein.

73. Defendants are strictly liable to Plaintiff under Pennsylvania Law.

74. Defendants have engaged in the business of designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling, testing, and/or distribution of the Defective Device. Through that conduct, Defendants knowingly and intentionally placed the Defective Device into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff.

75. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released the Defective Device into the stream of commerce in a condition which rendered it unreasonably dangerous due to its propensity to result in early failure of the device. The Defective Device was unreasonably dangerous in construction and/or composition.

76. Defendants expected the Defective Device to reach, and it did in fact reach, implanting orthopedic surgeons, health care professionals and consumers, including Plaintiff and Plaintiff's health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

77. The Defective Device, as manufactured and/or supplied by Defendants, was defective due to its high early failure rate. Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

78. The Defective Device was defective and unsafe such that it was unreasonably dangerous when it left the Defendants' possession and/or control, was distributed by Defendants, and implanted by Plaintiff's surgeon.

79. The Defective Device design created an unreasonable risk of early failure and resulting painful revision surgery.

80. This defect caused serious injury to Plaintiff, who used the Defective Device for its intended purpose and in a reasonably anticipated manner.

81. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as necessary to ensure the Defective Device did not cause users to suffer from unreasonable and dangerous risks.

82. Defendants negligently and recklessly designed, distributed, and promoted the Defective Device.

83. Defendants, as designers, manufacturers, sellers, and/or distributors of medical devices, are held to the knowledge of an expert in the field.

84. Plaintiff could not have discovered any defects in the Defective Device through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

85. The Defective Device, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably intended manner without knowledge of this risk of serious bodily harm.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

THIRD CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

86. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs excluding the previously named first and second causes of action, with the same force and effect as if more fully set forth herein.

87. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning the Defective Device, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

88. Defendants disseminated to health care professionals and consumers – through published labels, marketing materials, direct communications, and otherwise – information that misrepresented the efficacy and longevity of the Defective Device with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to implant the Defective Device.

89. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device knew, or reasonably should have known, that health care professionals and consumers of the Defective Device would rely on information disseminated

and marketed to them regarding the product when weighing the potential benefits and potential risks of implanting Defective Device.

90. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the efficacy and longevity of the Defective Device was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

91. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device, knew or reasonably should have known that surgeons would implant the Defective Device in reliance on the information disseminated by Defendants, and that the patients implanted with the Defective Device would suffer early failure and require revision surgery because the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff, was materially inaccurate, misleading, or otherwise false.

92. From the time the Defective Device was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety, efficacy, and longevity of the Defective Device. Defendants made material misrepresentations to Plaintiff, Plaintiff's health care professionals, the healthcare community, and the general public, including:

- a. Stating that the Defective Device had been tested and found to be safe and effective implant for TKA;

- b. Concealing, misrepresenting, and actively downplaying the severe risks of harm related to the implantation of the Defective Device, as compared to comparable alternative TKA devices; and
- c. Misrepresenting the Defective Device's risk of unreasonable and dangerous early failure.

93. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

94. These representations were made directly by Defendants, their sales representatives, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public, including Plaintiff and Plaintiff's physicians.

95. Defendants made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Defective Device.

96. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that the Defective Device had been tested and found to be a safe and effective TKA implant option.

97. The misrepresentations made by Defendants, in fact were false and known by Defendants to be false at the time the misrepresentations were made.

98. Defendants failed to exercise ordinary care in making their representations concerning the Defective Device and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Defective Device.

99. Defendants engaged in a nationwide marketing campaign, over-promoting the Defective Device in written marketing literature, in written product packaging, and in direct-to-

consumer advertising via print and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of Defective Device while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to patients implanted with the Defective Device, when compared to comparable alternative TKA implant options. Defendants negligently misrepresented the Defective Device's safety, efficacy, and longevity.

100. Defendants' conduct, as described above, was reckless. Defendants risked the health of consumers and users of the Defective Device, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions for years not to redesign or re-label, or to adequately warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

101. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a painful knee revision surgery and other related health complications. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

FOURTH CAUSE OF ACTION
PUNITIVE DAMAGES

102. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

103. At all times material hereto, the Defendants knew or should have known that the Defective Device was inherently more dangerous with respect to the risk of polyethylene wear and/or tibial tray loosening and a shorter life span and need for additional surgeries than the alternative knee replacement systems on the market.

104. At all times material hereto, the Defendants attempted to misrepresent, and did misrepresent, facts concerning the safety of the subject product.

105. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety and efficacy of the subject product.

106. At all times material hereto, the Defendants knew and recklessly disregarded the fact that Defective Device was subject to polyethylene wear and/or tibial tray loosening in persons implanted with the device with far greater frequency than safer alternative knee replacement systems.

107. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods, and fraudulently claimed that the Defective Device was superior in wear characteristics and longevity.

108. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff, in conscious disregard of the foreseeable harm.

109. Defendants knew and had knowledge of Foreign Registry data showing high failure rates and failed to disclose this information to implanting physicians. Further, Defendants failed to provide updated information so as to educate physicians to monitor patients that had previously implanted devices.

110. The Defendants intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff and her surgeons of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

111. As a direct and proximate result of the Defendants conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe and permanent physical injuries as set forth above.

112. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

113. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

- a) For general damages in a sum in excess of \$75,000, the jurisdictional minimum of this Court;
- b) For medical, incidental and hospital expenses according to proof;
- c) For pre-judgment and post-judgment interest as provided by law;
- d) For consequential damages in excess of the jurisdictional minimum of this Court;
- e) For compensatory damages in excess of the jurisdictional minimum of this Court;
- f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to deter similar conduct in the future and punish the Defendants for the conduct described herein;
- g) For attorneys' fees, expenses and costs of this action; and
- h) For such further and other relief as this Court deems necessary, just and proper.

Dated: January 9, 2018

Respectfully submitted,

VILLARI, BRANDES & GIANNONE, P.C.

/s/ Peter M. Villari

Peter M. Villari

Pennsylvania Bar No. 26875

8 Tower Bridge

161 Washington Street, Suite 400

Conshohocken, PA 19428

Telephone: (610) 729-2900, ex. 201

Facsimile: (610) 729-2910

pvillari@villarilaw.com